UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION, Plaintiff,	)	
v.	)	Civil Action 94-1306 (RCL)
JANE E. HENNEY, in her official capacity as Commissioner, Food and Drug Administration,[1] and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	

MEMORANDUM OPINION

This matter comes before the Court on defendants' motion to amend the Court's July 30, 1998 Order Granting Summary Judgment and Permanent Injunction. On February 16, 1999, the Court granted defendants' motion in part and denied it in part;[2] the

[1]Jane E. Henney, M.D., Commissioner of the FDA, is automatically substituted for former Acting Commissioner Michael Friedman, pursuant to Federal Rule of Civil Procedure 25(d).

[2]The Court amended the Order Granting Judgment and Permanent Injunction to clarify its application only to drugs and devices approved by the FDA for some use. The Court denied defendants' request, however, to limit the order's applicability to the three Guidance Documents embodying the FDA's policies at the time of the July 30, 1998 decision. The Court held that its decision declared unconstitutional the underlying FDA policies, not merely the Guidance Documents. See WLF v. Friedman, 36 F. Supp. 2d 16, 19 (D.D.C. 1999).

Court also requested that the parties submit supplemental briefs addressing "the issues raised by the recently effective FDAMA [Food and Drug Administration Modernization Act] and its implementing regulations," in light of this Court's July 30, 1998 ruling striking down several FDA policies as unconstitutional. Upon consideration of the plaintiff's and defendants' supplemental briefs, the record in this case, and the applicable law, the Court will deny the defendant's motion to amend insofar as it seeks to exclude the FDAMA from the scope of the July 30, 1998 order, and amend the order to reflect the unconstitutionality of the FDAMA and its implementing regulations.

I. BACKGROUND

The facts of this case are set forth in detail in the Court's July 30, 1998 memorandum opinion. See WLF v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998). In that decision, the Court granted summary judgment against the defendants, holding that the FDA was violating the First Amendment rights of plaintiff's members by unduly limiting the manner in which drug manufacturers may disseminate information relating to unapproved--or "off-label"--uses of FDA-approved drugs.[3]

At the time of this Court's July 30, 1998 decision, the

[3]As in the Court previous opinions in this case, the term "drug" refers both to drugs and devices regulated by the FDA.

FDA's unconstitutional policies were embodied in three Guidance Documents regulating the dissemination of journal articles and reference texts and manufacturer support of continuing medical education (CME) activities. However, as the Court anticipated in its July 30, 1998 decision, the Guidance Documents were superseded on November 21, 1998 by the Food and Drug Administration Modernization Act (and implementing regulations issued by the FDA). The provisions of the FDAMA perpetuate in part and modify in part the policies contained in the Guidance Documents. In particular, the FDAMA permits a drug manufacturer to disseminate journal articles and reference texts only under certain conditions, including the following:

1. The drug must be the subject of an approved application or otherwise lawfully marketed.

2. The disseminated information must be unabridged, not false or misleading, and not pose a significant risk to the public health.

3. The information must not be derived from clinical research by another manufacturer without that manufacturer's permission.

4. The manufacturer must submit an advance copy of the information to be disseminated to FDA along with any clinical trial information and reports of clinical experience.

5. The manufacturer must submit a supplemental new drug application for the off-label use or have certified that such an application will be submitted within the applicable statutory deadline, unless the Secretary determines that the manufacturer is exempt from this requirement because a) such supplemental application would be prohibitively expensive or b) it would be unethical to conduct the necessary studies.

6. The disseminated information must include a prominent disclosure that a) the material concerns an off-label use not approved by the FDA; b) the material is disseminated at the manufacturer's expense; c) identifies the authors of the information that have received compensation from or have financial interests in the manufacturer; d) includes the product's current approved labeling; e) includes a statement that there exist products approved for the particular intended use (if applicable); f) identifies the person providing funding for a study of the off-label use; and g) gives a bibliography of other scientific articles concerning the off-label use.

7. The manufacturer must prepare and submit semi-annually to the FDA lists of the articles and reference publications disseminated and the categories of recipients.

See Defs.' Suppl. Memo. at 7-8; 21 U.S.C. § 360aaa. The plaintiff objects to most of these requirements (most forcefully

to the last four) as unconstitutional and inconsistent with this Court's July 30, 1998 order and injunction. Defendants contend that, to the extent the FDAMA is inconsistent with the July 1998 order, the Court should amend that order to exclude from its scope the FDAMA and its implementing regulations.

On February 16, 1999, this Court denied defendants' motion to amend the judgment insofar as it sought to limit the applicability of the July 30, 1998 order solely to the Guidance Documents in effect at the time the order was issued, rather than to the underlying policies contained in those documents. See 36 F. Supp. 2d at 19. That decision squarely raised for the Court's consideration the issue of the FDAMA's validity in light of the July 30, 1998 judgment and injunction. Preferring to address that issue with due deliberation after hearing from both sides, the Court requested supplemental briefs from the parties specifically addressing the FDAMA and its implementing regulations. Based on that briefing, the Court now holds that the FDAMA largely perpetuates the policies held unconstitutional by the Court on July 30, 1998 and therefore may not be applied or enforced by FDA. Defendant's motion to amend the Order Granting Summary Judgment and Permanent Injunction will be denied in relevant part, although the Court will amend the order sua sponte to reflect the Court's determination that the FDAMA and its implementing regulations are unconstitutional.

II. DISCUSSION

As an initial matter, it may be helpful more clearly state the issue before the Court today. Read in the most narrow sense, defendants' motion could be viewed as simply a Rule 60 motion to amend the language of the July 30, 1998 order to exclude the FDAMA from the scope of the permanent injunction. From this perspective, the issue before the Court would be simply the extent to which the provisions of the FDAMA are covered by the injunction and, if covered, whether the injunction should be amended to exclude them. This articulation of the issue is, however, unduly narrow.

As reiterated in this Court's decision of February 16, 1999, the principal issue in this case has always been whether the FDA has unconstitutionally burdened plaintiff's First Amendment rights. The FDAMA and its implementing regulations have altered, to some extent, the FDA's policies regarding the dissemination of articles and texts relating to off-label uses. The true issue in controversy on the present motion, therefore, is whether the changes in FDA policy effected by the FDAMA have brought the FDA into compliance with the First Amendment. In other words, is the FDA unconstitutionally burdening free speech <u>today</u>? This question requires that the Court consider the defendants' motion as one for reconsideration in light of recent changes in the controlling law.

Upon review, the Court is persuaded that the decisions of July 30, 1998 and February 16, 1999 did and do correctly state the law applicable to this case, and the Court incorporates its prior review of the caselaw without repeating it here. The question before the Court, therefore, is whether the FDA's policies as currently embodied in the FDAMA[4] are unconstitutional under the legal standard stated by the Court in those decisions.

A. The Central Hudson Test Applies

As in its previous decision of July 30, 1998, the Court will analyze the constitutionality of the FDA's policies (as now contained in the FDAMA) under the four-prong inquiry articulated by the Supreme Court in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980), for judicial review of commercial speech regulations. Under Central Hudson, the court looks first to determine whether the speech at issue is false or inherently misleading. If the speech is truthful and nonmisleading, the government must demonstrate a substantial interest that is directly advanced by the regulation without burdening substantially more speech than necessary. See id.

[4]As defendants note in their supplemental memorandum, the FDA regulations issued pursuant to the FDAMA, while adding some detail to the language of the FDAMA, do not differ materially from the act itself. For ease and clarity, the Court will refer only to the act from here forward.

Before applying the Central Hudson analysis, however, one preliminary issue should be disposed of. Defendants make the argument in their supplemental briefs that the Court should not apply First Amendment commercial speech scrutiny to the FDAMA because, in defendants' words, the act "affirmatively permits" speech so long as it complies with the requirements of the statute. This is, of course, preposterous. The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity. To give an extreme and obvious example, the government could not justify a law criminalizing criticism of the government on the theory that such a law would "affirmatively permit" pro-government speech. Neither can the FDA escape judicial review of its speech restrictions on the theory that they "permit" speech that complies with the FDA's wishes.[5]

That said, the Court will turn to its Central Hudson analysis.

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[5]The Court is similarly unpersuaded by the argument that the FDAMA "privileges" the speech at issue by guaranteeing that it will not be considered evidence of misbranding by the manufacturer, so long as it complies with the statutory requirements. Even if the FDA would be justified in bringing misbranding charges on the basis of such speech, that power cannot justify the FDAMA's restrictions on commercial speech. See 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 511-12 (1996) (rejecting "greater power includes the lesser power" argument).

B. The Speech is Neither Unlawful Nor Inherently Misleading

First, the Court reiterates its prior holding that the speech at issue here is neither false nor inherently misleading. See 13 F. Supp. 2d at 66-67. It is a difficult contention indeed that the medical and scientific articles and reference texts at issue in this case are "inherently misleading." To the contrary, the defendants themselves admit to the importance of ensuring the availability of such information to physicians and health care providers making prescription and treatment decisions. Rather, the defendants argue that the manufacturers' dissemination of such information is likely to be misleading because manufacturers have an incentive to disseminate information that presents their drugs only in a positive light, omitting negative information and failing to provide the "balance" that the FDA would prefer.

This argument must fail, for at least two reasons previously stated by the Court. First, "potentially misleading" speech is not proscribable under the First Amendment. See id. The FDA may not restrict speech based on its perception that the speech could, may, or might mislead. Rather, for the protections of the First Amendment to fall away, the government must demonstrate that the restricted speech, by nature, is more likely to mislead than to inform, see id., a demonstration which the defendants have not made here. Second, defendants' true perception of the

speech at issue here is revealed by their attitude toward the same speech disseminated under other circumstances. See id. at 67. For example, defendants have no concern over the exchange of article reprints and reference texts among physicians; more telling, defendants do not even object to a manufacturer providing such information to a health care provider upon such person's request. See id. Only when the manufacturer initiates the exchange does the FDA choose to label the speech false or inherently misleading. The Supreme Court has recently addressed this situation with the following observation: "Even under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment." Greater New Orleans Broad. Assoc. v. United States, 119 S. Ct. 1923, 1935 (1999).

C. The Government Has A Substantial Interest

In its July 30, 1998 decision, this Court identified two governmental interests at issue in this case: 1) ensuring that physicians receive accurate and unbiased information upon which to make prescription decisions, and 2) encouraging drug manufacturers to seek FDA-approval of off-label uses. The Court found the first of these interests unavailing and the second

substantial, a determination that the Court reaffirms today.[6]

However forcefully the FDA argues the need to ensure a "balanced" flow of information to health care providers, the position articulated by this Court in its July 30, 1998 opinion remains true. The government, however benign its motivations, simply cannot justify a restriction of truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information. See 13 F. Supp. 2d at 69-70 (and cases cited therein). As the Court noted previously, this axiom is particularly powerful where the recipient of information is a sophisticated listener trained extensively in the use of such information--as are the doctors and other health care providers in this case. To the extent that the policies contained in the FDAMA are premised on the FDA's goal of protecting health care providers from misusing truthful, nonmisleading information, those policies violate the First Amendment.

The second interest advanced by defendants, and accepted by the Court in its previous ruling, is that of encouraging manufacturers to seek FDA approval of uses not yet on the labels

[6]Both of these interests, of course, are derivative of the government's recognized interest in protecting and promoting the public health, an interest of particular importance to the FDA. For purposes of a Central Hudson analysis, however, a more narrow definition of interests is more helpful.

of their products. Congress has determined that mandatory FDA approval of all drug uses benefits the public health, and absent a showing of unsupportable paternalism such as that rejected above or some other essential flaw, the Court accepts Congress's judgment on this matter. The Court reaffirms its conclusion that the government has a substantial interest in encouraging drug manufacturers to seek approval of off-label uses.

D. Only One of the Policies Contained in the FDAMA Directly Advances the Substantial Government Interest in Encouraging Manufacturers to Seek FDA Approval of Off-label Uses

The FDAMA contains many provisions restricting manufacturer-sponsored dissemination of articles and reference texts. The majority of these provisions (for example, that requiring attachment of a bibliography of related information) directly advance the FDA's stated goal of ensuring that physicians receive accurate and balanced information. As explained above, however, that is not a substantial interest that might justify the FDA's restrictions on speech.

In contrast, only one requirement of the FDAMA can be said to directly advance the substantial governmental interest in encouraging supplemental drug applications.[7] The FDAMA states

[7]The argument could perhaps be made that the other provisions of the FDAMA also encourage supplemental applications

that a manufacturer may disseminate information on off-label uses only if it has met one of the following three requirements: 1) it has submitted a supplemental application for approval of the off-label use, 2) it has certified to the FDA that such supplemental application will be forthcoming as provided in the statute, or 3) the Secretary has determined that the manufacturer is exempt from this requirement because the supplemental application would be economically prohibitive or would require unethical studies. See 21 U.S.C. § 360aaa-3(d). It is abundantly clear that this requirement directly advances the interest in encouraging supplemental applications. Indeed, any manufacturer that wishes to disseminate article reprints or reference texts (on its own initiative) has no choice but to submit a supplemental application.

E. The Supplemental Application Requirement Is Unconstitutional Because It Burdens Substantially More Speech Than Necessary

The problem with the FDAMA is not its effectiveness in encouraging supplemental drug applications, but rather the means

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simply because they make speech about off-label uses more cumbersome. This argument is immediately suspect because (like the supplemental application requirement discussed below) it restricts constitutionally protected speech as an incentive device. Furthermore, whatever incentive the provisions do create cannot reasonably be said to advance the government's interest in a "direct and material way."

by which it encourages such applications. The supplemental application requirement of the act amounts to a kind of constitutional blackmail--comply with the statute or sacrifice your First Amendment rights. It should go without saying that this tactic cannot survive judicial scrutiny.

Although the government may certainly choose (within the bounds of the Constitution) its own means to achieve its legitimate ends, it is worth noting here a few of the means that Congress and the FDA have not chosen to effectuate the substantial interest in encouraging manufacturers to seek FDA approval of off-label uses. The government has not chosen to ban the prescription of drugs for off-label uses. It has not chosen to prohibit manufacturers from profiting from off-label prescriptions. It has not chosen to impose a fine or other pecuniary penalty on manufacturers for failure to seek supplemental applications, nor has it chosen to more stringently enforce its statutory authority to prosecute misbranding. Instead, Congress and the defendants have chosen to condition the exercise of rights guaranteed by the United States Constitution upon the submission of a supplemental drug application. Such a gross imposition upon free speech is in clear violation of the First Amendment, and it cannot stand.

It also bears repeating that there currently do exist numerous incentives for manufacturers to seek approval of off-

label uses. Under the Court's narrowly applicable injunction, manufacturers are still much more limited in their promotion of off-label uses than in the promotion of approved uses. The manufacturers are also undoubtedly aware of the value of FDA approval as an indication of safety and reliability, certainly important factors for health care providers choosing between competing products as they make prescription decisions.

The existing factors encouraging supplemental applications, along with the many non-speech-restrictive alternatives available to the government, highlight the degree to which the FDAMA unduly burdens commercial speech. The supplemental application requirement burdens substantially more speech than necessary to advance the government's legitimate interest, and it therefore violates the First Amendment.

III. CONCLUSION

In conclusion, the Court finds that the FDAMA unconstitutionally restricts protected commercial speech. Therefore, the Court will deny defendants' motion to amend the July 30, 1998 order. The Court will, however, amend the order sua sponte to explicitly declare unconstitutional and unenforceable the FDAMA and its implementing regulations. The order, as amended this date and on Fenruary 16, 1999, shall be effective immediately.

A separate order will issue this date.

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Royce C. Lamberth
United States District Judge

DATE:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION, Plaintiff, v. JANE E. HENNEY, in her official capacity as Commissioner, Food and Drug Administration, and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	Civil Action 94-1306 (RCL)

ORDER

Upon consideration of the supplemental briefs in support of and opposition to defendants' motion to alter or amend the judgment, and for the reasons set forth in the memorandum opinion issued this date, the defendants' motion is hereby DENIED in relevant part.

Having found the Food and Drug Administration Modernization Act and its implementing regulations unconstitutional, the Court hereby AMENDS, sua sponte, its Order Granting Summary Judgment and Permanent Injunction, issued July 30, 1998, to explicitly declare the FDAMA and its implementing regulations unenforceable. A Final Amended Order Granting Summary Judgment and Permanent Injunction, reflecting all amendments to the order, will be

issued this date.

SO ORDERED.

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Royce C. Lamberth
United States District Judge

DATE:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION, Plaintiff, v. JANE E. HENNEY, in her official capacity as Commissioner, Food and Drug Administration, and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	Civil Action 94-1306 (RCL)

FINAL AMENDED ORDER GRANTING SUMMARY JUDGMENT AND PERMANENT INJUNCTION

This action is before the Court on the Cross-Motions for Summary Judgment filed by Plaintiff Washington Legal Foundation ("WLF") and defendants Jane E. Henney and Donna Shalala.

Having reviewed the memorandum and other materials submitted, having heard oral argument and otherwise being fully advised;

THE COURT FINDS that there are no genuine issues of material fact and that WLF is entitled to judgment as a matter of law; accordingly,

THE COURT GRANTS WLF's Motion for Summary Judgment;

THE COURT DENIES Defendants' Cross-Motion for Summary Judgment;

THE COURT FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Reprint Guidance"), Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Textbook Guidance"), and Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (Dec. 3, 1997) (the "Final CME Guidance"), are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.

THE COURT FURTHER FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Food and Drug Administration Modernization Act, 21 U.S.C. §§ 360aaa through 360aaa-6, and in the FDA's Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. Part 99, are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.

THE COURT HEREBY ENJOINS Defendants, their successors, and all persons acting in concert with them or otherwise purporting to act on behalf of the United States (collectively "Defendants") from application or enforcement of any regulation, guidance, policy, order or other official action , as follows:

1. Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:

a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previous published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

b) from disseminating or redistributing to physicians or other medical professionals any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses;

c) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether unapproved uses for drugs or medical devices that are approved by FDA for other uses are to be discussed.

2. For purposes of this injunction, a "bona fide peer-reviewed journal" is a journal that uses experts to objectively review and select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal.

3. For purposes of this injunction, a "bona fide independent publisher" is a publisher that has no common ownership or other corporate affiliation with a pharmaceutical or

medical device manufacturer and whose principal business if the publication and distribution of books through normal distribution channels.

4. For purposes of this injunction, an "independent program provider" is an entity that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer, that engages in the business of creating and producing continuing medical education seminars, programs or other symposia and that is accredited by a national accrediting organization pertinent to the topic of the seminars, programs or symposia.

5. Nothing herein shall be construed to limit Defendants' application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. In addition, Defendants may require any pharmaceutical or medical device manufacturer that sponsors or provides financial support for the dissemination or redistribution of articles or reference textbooks or for seminars that include references to unapproved uses for drugs or medical devices that are approved by FDA for other uses to disclose (i) its interest in such drugs or devices, and (ii) the fact that the use discussed has not been approved by FDA.

6. Defendants shall cause this injunction to be published in the Federal Register within 15 days of the date hereof.

IT IS SO ORDERED on this _____ day of _____, 1999.

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THE HONORABLE ROYCE C. LAMBERTH
United States District Judge